

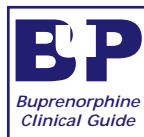
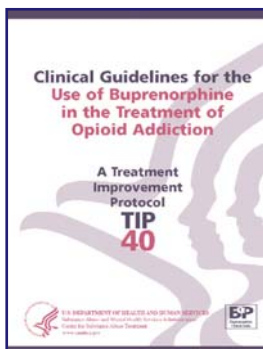
Quick Guide

For Physicians

Based on TIP 40

***Clinical Guidelines for the
Use of Buprenorphine in the***

***Treatment
of Opioid
Addiction***



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
www.samhsa.gov

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Quick Guide

For Physicians

Based on TIP 40

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction

This Quick Guide is based entirely on information contained in TIP 40, published in 2004. No additional research has been conducted to update this topic since publication of TIP 40.

WHY A QUICK GUIDE?

This Quick Guide was developed to accompany *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, Number 40 in the Treatment Improvement Protocol (TIP) series published by the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA). This Quick Guide is based entirely on TIP 40 and is designed to meet the needs of the busy physician for concise, easily accessed how-to information.

The Guide is divided into eight sections (see *Contents*) to help readers quickly locate relevant material. The Guide will help physicians make practical and informed decisions about the use of buprenorphine to treat opioid dependence.

For more information on the topics in this Quick Guide, readers are referred to TIP 40.

WHAT IS A TIP?

The TIP series has been in production since 1991. This series provides the substance abuse treatment and related fields with consensus-based, field-reviewed guidelines on substance abuse treatment topics of vital current interest.

TIP 40, *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, provides step-by-step guidance through the opioid dependence treatment decisionmaking process. Using these guidelines, physicians should be able to

- Perform initial screening and assessment of patients with opioid addiction
- Determine the appropriateness of buprenorphine treatment for these patients
- Provide treatment of opioid addiction with buprenorphine according to established protocols
- Assess for the presence of and arrange appropriate treatment for co-occurring medical and mental disorders
- Determine when to seek specialty addiction treatment referral or consultation.

See the inside back cover for information on how to order TIPs and other related products.

INTRODUCTION

The Drug Addiction Treatment Act of 2000 (DATA 2000) made it possible for physicians to treat opioid dependence in their own practices with Schedule III, IV, or V opioid medications that have been approved by the U.S. Food and Drug Administration (FDA) for that indication. In October 2002 FDA approved the first of these medications to treat opioid addiction—buprenorphine, a Schedule III opioid medication.

The approved formulations—Subutex[®] and Suboxone[®]—are administered sublingually. They can be prescribed or dispensed by qualified physicians in any appropriate clinical settings. To prescribe and dispense buprenorphine, physicians must obtain a waiver as stipulated in DATA 2000. To qualify for a DATA 2000 waiver, physicians must attest that they can provide or refer patients for appropriate counseling or other psychosocial services. They must also have done at least one of the following (see p. 33 of this Quick Guide for more detailed information):

- Completed training or acquired experience in the treatment of patients who are opioid dependent
- Attained certification in addiction medicine or addiction psychiatry

- Participated as an investigator in a clinical trial leading to the approval of a narcotic drug in Schedule III, IV, or V for maintenance or detoxification treatment.

Buprenorphine's usefulness stems from its pharmacological and safety profile:

- Its partial agonist properties
- Its high affinity for mu opioid receptors
- Its low intrinsic activity at mu opioid receptors
- Its slow dissociation rate.

To keep abreast of advances in training and research on buprenorphine treatment of opioid addiction, physicians should

- Seek the advice of addiction specialists when this Quick Guide and TIP 40 do not answer their questions about the use of buprenorphine
- Refer to the SAMHSA Buprenorphine Web site at www.buprenorphine.samhsa.gov.

For more detailed information, see TIP 40, pp. 1–9.

PHARMACOLOGY

The Three Types of Opioid Drug–Receptor Interactions

- **Full agonists** are drugs that bind to mu opioid receptors in the brain, producing analgesic, euphorogenic, and addictive effects. The presence of higher levels of an agonist causes more receptors to be activated, producing greater effects. Heroin, oxycodone, and morphine are full agonists for the mu receptor.
- **Antagonists** block receptor molecules, with no activation and no opioid effects. When attached, the antagonists prevent other molecules from binding. Naloxone and naltrexone are opioid antagonists.
- **Partial agonists** bind to receptors and activate them but to a lesser extent than full agonists. When dosages are increased, both full and partial agonists produce greater effects. However, at a certain point, increases in the amount of a partial agonist cease to create greater effects. A ceiling is reached. At high dosages, partial agonists can act as antagonists, blocking and not activating receptors.

Buprenorphine is a partial agonist. Buprenorphine doses beyond the ceiling point prolong buprenorphine's effects but do not produce

greater effects. As a result, compared with full opioid agonists, buprenorphine has

- Lower abuse potential
- Lower level of physical dependence
- Less withdrawal discomfort
- Greater safety in overdose.

Properties of Buprenorphine

- **High affinity for receptors.** It cannot be displaced by full agonists and displaces full agonists already bound to receptors, thereby blocking their effects.
- **Low intrinsic activity.** It activates receptors only moderately.
- **Slow dissociation rate.** Its effects persist for a long time.

Buprenorphine is absorbed poorly from the gastrointestinal tract. FDA-approved formulations for the treatment of opioid dependence are sublingual tablets.

Uses of Buprenorphine

Buprenorphine can be used for long-term maintenance and for medically supervised withdrawal (MSW).

- **Maintenance treatment.** Appropriate dosages of buprenorphine are more effective than low dosages (20–35 mg) of methadone. A

buprenorphine dosage of 8–16 mg/day is equivalent to about 60 mg/day of methadone.

- **MSW.** Buprenorphine has been used with some success to aid in long-period (more than 30 days) withdrawal from opioids, in moderate-period (between 3 and 30 days) withdrawal, and in short-period (3 days or fewer) withdrawal. However, supervised withdrawal usually is less effective than long-term medical maintenance.

Buprenorphine Abuse and Naloxone

Consistent with its action at the mu opioid receptor, buprenorphine is abusable. But its abuse potential is lower than that of full opioid agonists.

In individuals who are nonphysically dependent opioid users, buprenorphine taken parenterally or sublingually can produce opioid-like effects. The addition of naloxone (in the buprenorphine/naloxone combination tablet) does not attenuate the opioid effects of sublingual buprenorphine in this population.

In individuals who are physically dependent on opioids, the potential for abuse varies based on the following:

- **Level of physical dependence.** Buprenorphine can produce opioid agonist effects in individuals with a low level of physical dependence but may

cause withdrawal effects in individuals with a high level of physical dependence.

- **Time interval.** If taken within a short period of a dose of agonist, buprenorphine can cause withdrawal effects.
- **Dose.** High doses of injected buprenorphine can cause effects resembling those of opioid agonists.

To lower the potential for abuse, especially by injection, scientists developed a combination tablet containing buprenorphine and naloxone. When this combination tablet is dissolved under the tongue, buprenorphine's effects predominate. However, when the tablet is dissolved and injected into the bloodstream, the undesirable effects (withdrawal symptoms) of naloxone predominate.

Side Effects

The primary side effects of buprenorphine

- Are similar to those produced by full mu opioid agonists (e.g., nausea, vomiting, constipation)
- Are less intense because buprenorphine is a partial agonist.

Safety

Safety advantages of buprenorphine include the following:

- Swallowing a buprenorphine tablet by accident may result in a mild effect.

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- Buprenorphine's ceiling effect reduces the risk of harm from overdosing.
- An overdose of buprenorphine does not appear to cause clinically significant respiratory depression.

Drug Interactions

- Physicians should be cautious about prescribing buprenorphine in combination with benzodiazepines or to patients who abuse or are addicted to benzodiazepines and other central nervous system depressants (including alcohol and barbiturates).
- Because buprenorphine is metabolized by the body's cytochrome P450 3A4 enzyme system, physicians should be cautious about prescribing other medications metabolized by this system. (See p. 21 of TIP 40 for a partial list of medication interactions; also see medicine.iupui.edu/flockhart/table.htm and the SAMHSA Buprenorphine Web site.)

For more detailed information, see TIP 40, pp. 11–24.

PATIENT ASSESSMENT

Screening

Potential buprenorphine patients should undergo standard initial screening to establish the presence of an opioid use disorder. Many screening instruments are available such as the Clinical Opiate Withdrawal Scale and the Drug Abuse Screening Test. (See appendix B in TIP 40, pp. 101–113, for screening and assessment instruments.)

Assessment

Patients often are reluctant to disclose drug use openly with physicians for the following reasons:

- They fear the loss of opioid pain medication.
- They fear the discomfort of withdrawal.
- They feel shame.

To encourage patients with an addiction to be forthcoming, physicians need to approach them in an honest, respectful, matter-of-fact way, just as they would any other patient.

If screening indicates that a patient has an opioid use disorder, the patient should be assessed to

- Delineate thoroughly the problem
- Identify co-occurring or complicating medical or mental conditions

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- Determine the appropriate treatment setting and level of treatment intensity.

Assessment should consist of

- Complete patient history
- Physical examination
- Mental status examination
- Relevant laboratory testing
- Formal psychiatric assessment (if indicated).

Of particular concern when performing a physical examination are

- Identifying opioid intoxication or overdose; opioid overdose should be treated as a medical emergency
- Identifying opioid withdrawal
- Assessing other substance intoxication and withdrawal syndromes
- Identifying co-occurring medical conditions common among individuals addicted to opioids, such as tuberculosis, HIV/AIDS, hepatitis B and C, and other sexually transmitted diseases.

Recommended baseline laboratory evaluations include

- Serum electrolytes
- BUN and creatinine
- CBC with differential and platelet count
- Liver function tests (GGT, AST, ALT, PT or INR, albumin)
- Lipid profile

- Urinalysis
- Pregnancy test (for women of childbearing age)
- Toxicology tests for drugs of abuse
- HIV antibody testing
- Hepatitis B and C screens.

Physicians also should obtain the following laboratory evaluations as indicated:

- Blood alcohol level (Breathalyzer™ or blood sample)
- Hepatitis A serology (in patients with hepatitis B virus [HBV] or hepatitis C virus [HCV] infection)
- Serology test for syphilis (Venereal Disease Research Laboratories test)
- Purified protein derivative test for tuberculosis, preferably with control skin tests.

Before testing for HIV and hepatitis C, physicians should provide appropriate counseling and obtain consent. Patients who test positive for HCV should be further evaluated and treated. HIV-positive status does not preclude buprenorphine treatment, but as-yet-unrecognized antiretroviral medication interactions with buprenorphine may interfere with treatment.

The assessment may occur in stages over a 3- to 4-week period during initiation of treatment.

Questions To Determine Whether Buprenorphine Treatment Is Appropriate

To be considered for buprenorphine maintenance, patients should meet the DSM-IV-TR criteria for a diagnosis of opioid dependence (see appendix C in TIP 40, pp. 115–118). Among the questions the physician should consider are the following:

- Are there current signs of intoxication or withdrawal or risk for severe withdrawal?
- Is the patient interested in and motivated for buprenorphine treatment?
- Does the patient understand the risks and benefits of buprenorphine treatment?
- Will the patient adhere to the treatment plan and follow safety procedures?
- Can the needed resources for the patient be provided (either on or off site)?
- Is the patient mentally stable?
- Is the patient pregnant?
- Is the patient dependent on or abusing alcohol or sedative-hypnotics?
- What is the patient's risk for continued opioid use or relapse to opioid use?
- Is the patient taking medications that may interact with buprenorphine?
- Does the patient have medical problems that are contraindications to buprenorphine treatment? Could physical illnesses complicate treatment?

- Is the patient's recovery environment stable and supportive?

Conditions and Circumstances That May Preclude a Patient as a Candidate for Office-Based Buprenorphine Treatment

- Co-occurring dependence on high doses of benzodiazepines or other central nervous system depressants (including alcohol)
- Significant untreated co-occurring mental disorders
- Active or chronic suicidal or homicidal ideation or attempts
- Poor response to previous well-conducted attempts at buprenorphine treatment
- Significant medical complications.

Cautions and Contraindications for Buprenorphine Treatment

- **Seizures.** When buprenorphine is used with antiseizure medications (e.g., phenytoin, carbamazepine), metabolism of buprenorphine and the antiseizure medication may be altered.
- **HIV treatment.** Patients infected with HIV have been treated successfully with buprenorphine. Buprenorphine should be used with caution in patients taking HIV antiretroviral medications that may inhibit, induce, or be metabolized by the cytochrome P450 3A4 enzyme system.

Studies on the interaction of buprenorphine with HIV medications are underway.

- **Hepatitis and impaired liver function.** Viral hepatitis (especially infection with HBV and HCV) is common among individuals who abuse opioids. Elevated liver enzymes do not contraindicate treatment with buprenorphine, but they should be evaluated and monitored frequently.
- **Pregnancy.** Methadone is the standard treatment for pregnant women who are addicted to opioids. Few studies exist on the use of buprenorphine in pregnant women. Buprenorphine is a Category C agent, which means that the benefits of using the drug in pregnant women may be acceptable despite the risk of adverse effects on the fetus (see Special Populations below for more information).
- **Use of other drugs.** Patients should abstain from the use of nonprescribed drugs while receiving buprenorphine treatment. Patients who use or abuse more than one substance present unique problems and may require referral for more intensive treatment.
- **Sedative-hypnotics.** Use of sedative-hypnotics (e.g., benzodiazepines, barbiturates) is a relative contraindication for treatment with buprenorphine because the combination can increase depression of the central nervous system and result in death. If treatment with buprenorphine

and sedative-hypnotics is necessary, the dosages of both may need to be lowered.

- **Alcohol.** Patients should abstain from alcohol while taking buprenorphine. Rarely are patients with active alcohol dependence appropriate candidates for office-based buprenorphine treatment. Buprenorphine will not control seizures caused by withdrawal from alcohol or other sedative-hypnotics.

For more detailed information, see TIP 40, pp. 25–47.

TREATMENT PROTOCOLS

Physicians who prescribe buprenorphine to treat opioid addiction should consider the entire treatment process, from induction through stabilization and maintenance. The buprenorphine/naloxone combination tablet (Suboxone) is recommended for induction, stabilization, and maintenance treatment for most patients. Patients who want to switch from long-acting opioids to buprenorphine may be inducted on monotherapy (Subutex) but should be switched to combination therapy as soon as possible (within 2 days).

Buprenorphine can precipitate withdrawal symptoms in patients who are opioid dependent and whose receptors are occupied by opioids. Patients should no longer be intoxicated or have residual effects from their last opioid dose before receiving a first dose of buprenorphine. Because they have been abstinent, patients often will experience the early stages of withdrawal. Too little buprenorphine may not completely alleviate spontaneous withdrawal. Physicians should consider patients' history and counsel patients about possible side effects.

Maintenance Treatment

The three phases of maintenance treatment are

- Induction
- Stabilization
- Maintenance.

Induction

During this phase (usually in the first week of treatment), the physician finds the minimum dosage of buprenorphine at which the patient discontinues use of other opioids and has no withdrawal symptoms, cravings, or side effects.

Days 1 and 2. On day 1 of the induction phase, physicians administer initial doses and then should observe the patient for up to 2 hours.

Patients who are not physically dependent should receive the lowest possible dose of buprenorphine/naloxone, 2/0.5 mg. Patients exhibiting signs of withdrawal whose last use of a short-acting opioid (e.g., heroin, oxycodone) was at least 12 hours before induction can receive a first dose of 4/1–8/2 mg of buprenorphine/naloxone combination. The total amount of buprenorphine administered in the first day should not exceed 8 mg.

Induction of patients from long-acting opioids (e.g., methadone) onto buprenorphine should be managed by physicians experienced with the procedure. Patients taking methadone should have their dose tapered to 30 mg or less per day for at least 1 week before buprenorphine induction. Twenty-four hours must elapse between the final dose of methadone and the first dose of buprenorphine. The first dose of buprenorphine should be 2 mg of

monotherapy. A second 2 mg dose can be given and repeated up to 8 mg per day if signs of withdrawal appear.

Day 2 and forward. Exhibit 1, pp. 22–23, charts the steps in the induction phase from day 2 and forward.

Stabilization

This phase can begin when the patient has

- No withdrawal symptoms
- Minimal side effects
- No uncontrollable cravings.

During stabilization (1 to 2 months), adjustments in dosage and frequent physician–patient contact establish the proper level of medication. Until full stabilization is achieved, weekly assessments are indicated. Doses of buprenorphine/naloxone may be increased in 2/0.5–4/1 mg increments until stabilization is achieved. Nearly all patients stabilize on daily doses of 16/4–24/6 mg; some may require up to 32/8 mg daily.

Maintenance

In this phase (which may be indefinite or relatively short), patient and physician have less contact, but

both should be vigilant. The presence of some or all of the following issues requires the continued provision of nonpharmacological services:

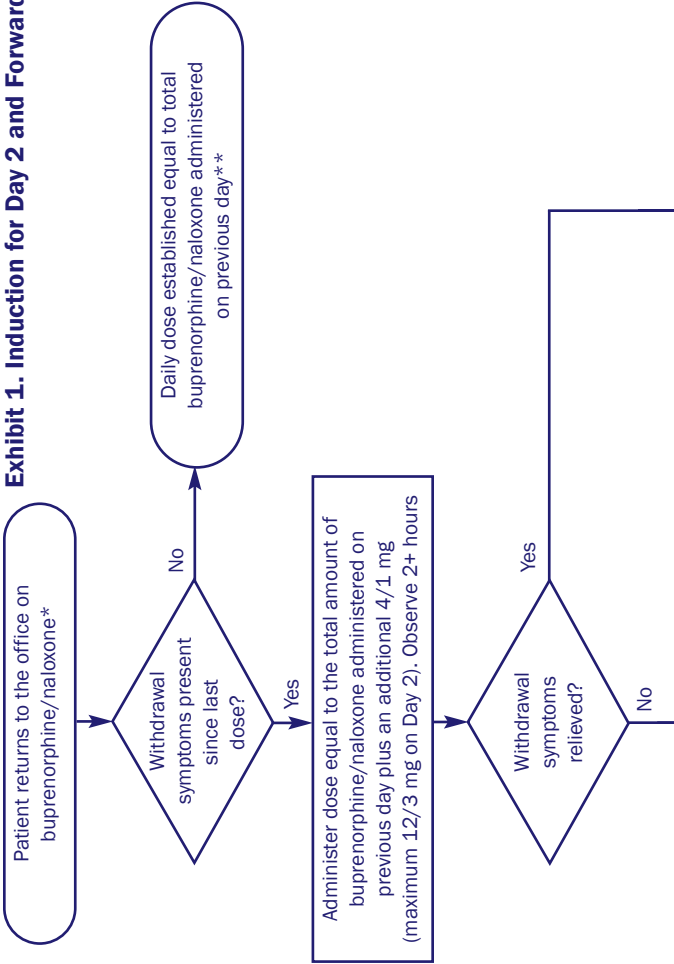
- Co-occurring mental disorders
- Somatic consequences of drug use
- Family and support issues
- Employment and financial issues
- Legal consequences of drug use
- Other drug and alcohol abuse.

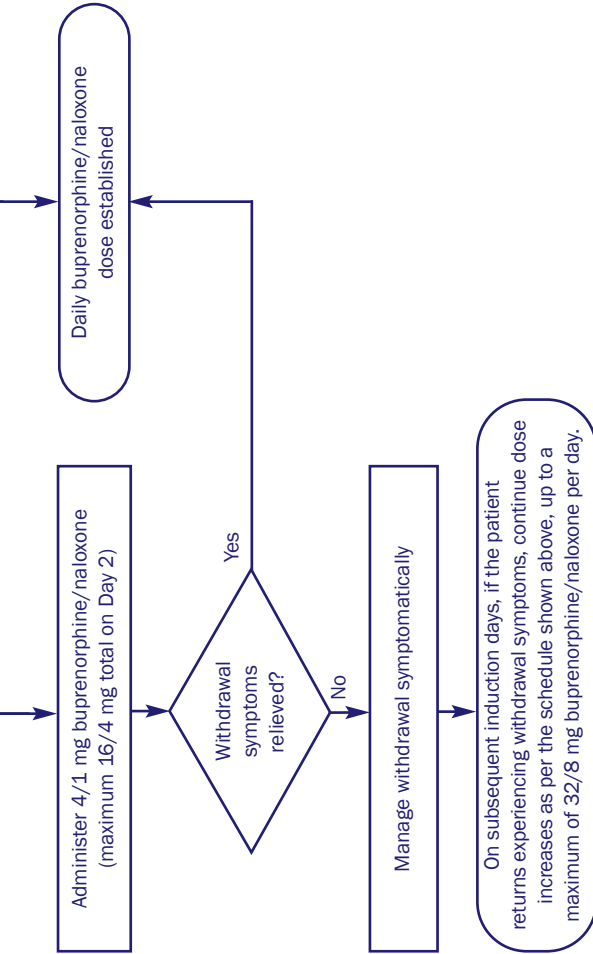
Note: Longer maintenance treatment is associated with less illicit drug use and fewer complications.

Long-term medication management. The design of long-term treatment depends on the patient's treatment goals and on objective signs of treatment success. After a patient is stabilized successfully, decisions to decrease or discontinue buprenorphine should be based on the patient's desire and commitment to become medication free and on the physician's confidence that tapering will be successful. Factors to consider when determining suitability for long-term medication-free status include

- Stable housing and income
- Adequate psychosocial support
- Absence of legal problems.

Exhibit 1. Induction for Day 2 and Forward





* If buprenorphine monotherapy was administered on Day 1, switch to buprenorphine/naloxone on Day 2 (for a patient who is not pregnant).

** Dose may be increased by 2/0.5–4/1 mg increments on subsequent days as needed for symptom relief. Target dose of 12/3–16/4 mg buprenorphine/naloxone per day by the end of the first week.

Buprenorphine for Detoxification

Buprenorphine can be used in MSW (also known as detoxification), which eliminates a patient's use of all short-acting opioids or transitions a patient out of opioid agonist treatment (methadone or LAAM). MSW from short-acting opioids involves two phases.

Induction phase

The objectives of induction during MSW are

- To stabilize the patient as rapidly as possible
- To minimize withdrawal symptoms
- To eliminate further use of illicit opioids.

When the patient ceases to use illicit opioids and begins to exhibit withdrawal signs, an initial dose of 4/1 buprenorphine/naloxone is given and repeated in 2–4 hours if indicated. Over the next 2 days, the dosage should be increased to 12/3–16/4 mg per day. When a patient has stopped using illicit opioids completely, the dose-reduction phase begins. Unless a patient is in a hospital or residential facility, cessation of opioid use should be documented with a negative toxicology test for illicit opioids.

Dose-reduction phase

Reduction leading to discontinuation of buprenorphine maintenance can occur over

- A short period (3 days)
- A moderate period (10 to 14 days or longer, during which dosage of buprenorphine is reduced by 2 mg every 2 or 3 days)
- A long period.

Longer period reduction is thought to be more effective than reduction over short or moderate periods, especially for patients who cannot engage in rehabilitation services without agonist support.

Buprenorphine for discontinuation of methadone or LAAM treatment

The use of buprenorphine to taper off methadone or LAAM treatment should be considered only for patients with sustained medical and psychosocial stability.

- Patients tapering from methadone often experience opioid withdrawal symptoms and craving when the dosage drops below 30 mg.
- Patients tapering from LAAM may begin to use buprenorphine when the LAAM dosage drops to 40 mg or less (per 48-hour dose).

Buprenorphine induction then can begin, following the guidelines presented above. Only a small proportion of these patients are likely to remain abstinent. If this tapering is unsuccessful, the patient may resume maintenance using buprenorphine/naloxone.

Discontinuing buprenorphine/naloxone

To discontinue buprenorphine/naloxone treatment, the physician should decrease the daily dose gradually at a rate agreed on by the patient and physician. Tapering the use of a buprenorphine/naloxone combination can lead to withdrawal symptoms, at which point tapering may be suspended temporarily.

Patient Management

Pharmacotherapy is rarely sufficient treatment for substance dependence. Physicians should refer patients for psychosocial services. Substance abuse counseling and participation in a mutual-help group are necessary for most patients. DATA 2000 stipulates that physicians must have the capacity to refer patients for appropriate counseling and other nonpharmacological therapies.

Patients and physicians should agree on treatment goals and devise a treatment plan. The plan should specify conditions that will result in treatment termination and contingencies for treatment failure.

Treatment contracts often are used to spell out patients' responsibilities.

During stabilization, physicians see patients at least weekly. Once a stable buprenorphine dosage is reached and the patient has stopped using illicit drugs, biweekly or monthly visits may be appropriate.

Measures used to evaluate maintenance treatment with buprenorphine include

- No illicit drug use and no other ongoing drug or problem alcohol use that might compromise patient safety
- Absence of toxicity
- Absence of medical adverse effects
- Absence of behavioral adverse effects
- Responsible handling of medication by patient
- Patient adherence to all elements of the treatment plan (e.g., seeing a psychotherapist, attending mutual-help groups as scheduled, participating in recovery-oriented activities).

Toxicology tests for all relevant illicit drugs should be administered monthly, usually by screening urine, although blood, saliva, sweat, and hair also can be tested.

For more detailed information, see TIP 40, pp. 49–66.

SPECIAL POPULATIONS

Before treating individuals with the following special circumstances for opioid addiction in an office setting, physicians should consider whether the patients' needs can be met in a physician's office or whether patients would be better served by a specialized program.

Co-Occurring Medical Problems

People addicted to opioids often present with other medical problems including

- HIV/AIDS
- Tuberculosis
- Hepatitis B and C
- Skin and soft tissue infections
- Syphilis and other sexually transmitted diseases
- Seizure disorders
- Valvular heart disease secondary to endocarditis
- Pulmonary hypertension secondary to talc granulomatosis
- Lymphedema
- Pseudoaneurysms of the neck and groin secondary to thrombophlebitis
- Renal insufficiency secondary to heroin-associated nephropathy.

Treating opioid addiction in patients with co-occurring medical conditions is likely to result in better outcomes for the co-occurring conditions

than would be achieved if the opioid use were not treated.

Pregnant Women and Neonates

The continued use of heroin during pregnancy is life threatening to both the woman and her fetus because of the risks of infection, overdose, and intrauterine withdrawal. Methadone is currently the standard of care in the United States and has been shown to be safe and effective in both pregnant women and neonates. Research on the safety, efficacy, and effects of buprenorphine used during pregnancy is scarce. However, if a patient is pregnant or is likely to become pregnant during opioid addiction treatment, the physician must consider whether buprenorphine is an appropriate treatment option. Physicians should document that the patient was informed of and understands the risks of treatment with buprenorphine. FDA classifies buprenorphine as a Category C agent, which means

- Animal reproduction studies have shown an adverse effect on the fetus
- There are no adequate, well-controlled human studies
- The benefits of buprenorphine in pregnant women may be acceptable despite its risks.

Although not systematically studied, a neonatal abstinence syndrome has been reported in infants born to women taking buprenorphine. Although no

randomized, controlled trials have been reported, the neonatal abstinence syndrome associated with buprenorphine has been reported to be less intense than that observed with methadone. The TIP 40 consensus panel believes that breast-feeding is not contraindicated in women who are maintained on buprenorphine (although Subutex and Suboxone package inserts advise against it).

Adolescents and Young Adults

Because of the relative ease of withdrawal, buprenorphine may be preferred to methadone for treatment of opioid addiction in adolescents. Physicians treating addiction in adolescents should be familiar with the laws in their State regarding parental consent.

Elderly Patients

Literature on the use of buprenorphine to treat geriatric patients is limited. Rates of metabolism and absorption may be different from those seen in the nonelderly, so physicians should exercise caution, especially during the induction phase of treatment.

Patients With Co-Occurring Mental Disorders

The presence and severity of co-occurring mental disorders (e.g., depression, posttraumatic stress disorder, antisocial or borderline personality disorders, alcoholism or other substance abuse)

should be assessed before or during initiation of buprenorphine treatment. Co-occurring mental conditions do not exclude patients from buprenorphine treatment. Patients with polysubstance abuse should be referred for treatment of their other addictions.

Patients With Pain

Patients who become physically dependent on opioids during medical treatment for pain should be treated in their regular medical or surgical setting, not transferred to an opioid treatment program. Pain in patients who receive buprenorphine treatment should be treated initially with non-opioid analgesics. If the pain is not relieved, short-acting opioids can be given and treatment with buprenorphine discontinued. To restart buprenorphine treatment, physicians should follow the induction guidelines discussed earlier.

Patients Recently Discharged From Controlled Environments

Patients recently released from prison or rehabilitation or returning from extended stays in countries where illicit opioids are difficult to obtain can be assumed to have undergone involuntary detoxification. Patient assessment should determine the diagnosis of opioid dependence or addiction and the risk of the patient's returning to an addiction lifestyle.

Health Care Professionals Who Are Addicted to Opioids

Buprenorphine may be an appropriate treatment option for health care professionals but should be part of a comprehensive, monitored recovery plan.

For more detailed information, see TIP 40, pp. 67–78.

POLICIES AND PROCEDURES

Obtaining a Waiver To Dispense

Buprenorphine

According to DATA 2000, to receive a waiver to treat patients with opioid addiction in their offices, physicians must

- Complete at least 8 hours of training in the treatment and management of patients who are opioid dependent; be certified in addiction psychiatry by the American Board of Medical Specialties, in addiction medicine by the American Osteopathic Association, or in addiction by the American Society of Addiction Medicine; have participated as an investigator in a clinical trial leading to the approval of a narcotic drug in Schedule III, IV, or V for maintenance or detoxification treatment as demonstrated by a statement submitted to the Secretary of the Department of Health and Human Services (DHHS) by the sponsor of such approved drug; or have acquired training or experience determined by a State medical licensing board or by the Secretary of DHHS to demonstrate the physician's ability to treat and manage patients who are opioid dependent
- Attest that they can provide or refer patients for appropriate counseling or other needed psychosocial services

- Submit notification of intent to SAMHSA (Notification of Intent forms can be downloaded from www.buprenorphine.samhsa.gov). Forms can be submitted electronically, faxed, or mailed.

After fulfilling these requirements, physicians are issued a special identification number and a waiver.

Preparing a Medical Practice for Opioid Treatment

Physicians should familiarize themselves with current research, treatment practices, and regulations relevant to office-based opioid treatment. Office procedures should be established, written, and clearly communicated, and staff members should be educated and trained about opioid addiction treatment. Links should be established with

- Local physicians who can provide office-based buprenorphine treatment when the treating physician is unavailable
- Local medical specialists who can treat patients' co-occurring medical conditions
- Local mental health specialists who can treat patients' co-occurring mental disorders
- Community referral sources such as mutual-help groups, case managers, and social workers.

Confidentiality

The privacy and confidentiality of patient information are protected under Federal law. Physicians should

- Establish office procedures that are in compliance with all Federal laws governing patient privacy
- Have patients sign a consent form when they start treatment with buprenorphine so that information can be disclosed to pharmacists and other health care providers.

SAMHSA-Certified Opioid Treatment Programs

Programs that already are certified by SAMHSA to offer methadone and LAAM treatment can provide treatment with Subutex and Suboxone without receiving a waiver. When adding treatment with buprenorphine, these programs must continue to provide medical services, counseling, and drug testing and need to change their registration with the Drug Enforcement Administration to add Schedule III narcotics.

For more detailed information, see TIP 40, pp. 79–85.

Ordering Information

TIP 40

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction

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2. Visit NCADI's Web site at **www.ncadi.samhsa.gov**
3. You can access TIPs online at **www.kap.samhsa.gov**



Other Treatment Improvement Protocols (TIPs) that are relevant to this Quick Guide:

TIP 24: *A Guide to Substance Abuse Services for Primary Care Physicians* (1997) **BKD234**

Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs
(Expected publication date 2005)

Detoxification and Substance Abuse Treatment
(Expected publication date 2005)

See the inside back cover for ordering information for all TIPs and related products.